

Update Instructions

SP005/04/P

Title: Extended High Voltage Power Supply for the FFDM-S a-SE Detector

Reason for Update:

☒ Performance

Urgency: ☐ Immediate ☒ Within 2 months

Update material required? ☒ Yes ☐ No

Materials free of charge? ☒ Yes ☐ No

Return of parts? ☒ Yes ☐ No

Estimated completion time: 21 working hours Number of CSE's: 1

Customer application training? ☐ Yes ☒ No

Systems/Products affected/System identifying IVK

Name	Material No.	Serial No.
See Table 1	See Table 1	See Table 1
n.a.	n.a.	n.a.

Remark: n.a.

Components affected/to be modified

Name	Material No.	Serial No.	Component status affected
n.a.	n.a.	n.a.	n.a.
n.a.	n.a.	n.a.	n.a.

Remark: n.a.

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Document Revision Level

This document corresponds to the version/revision level effective at the time of system delivery. Revisions to hardcopy documentation are not automatically distributed.

Please contact your local Siemens office to order current revision levels.

Disclaimer

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Systems/Products Affected

According to Table 1

System Name	Material No	Serial No	Component Name	Material No	Status
Novation	6646900	1003	Detector	6646710	Affected
Novation	6646900	1004	Detector	6646710	Affected
Novation	6646900	1005	Detector	6646710	Affected
Novation	6646900	1012	Detector	6646710	Affected
Novation	6646900	1013	Detector	6646710	Affected
Novation	6646900	1014	Detector	6646710	Affected

Table 1

Reason for the Update

The Full-Field Digital Mammography amorphous Selenium Digital Detector will be equipped with the Extended High Voltage Power Supply in order to improve its sensitivity. This in turn will allow for a decrease of dose.

Modified firmware containing some improvements will also be applied.

With immediate effect these changes will be incorporated into all detectors delivered in future.

NOTE

The update itself will be performed by dedicated personnel on behalf of the HQ; the local CSE is required to assist, provide some tools and test equipment, and help to perform measurements and tests before and after the update. The reimbursement is calculated for these activities.

Prerequisites

n.a.

Special Tools / Documents

Tools

A regular toolbox of the CSE, additionally in particular:

- soldering gun with solder;
- 3/32" - Allen wrench;
- Plus-driver P1 & P2;
- 5/16 - deep socket nut drive;
- Slotted screwdriver;
- Ground strap, (ESD;

Test equipment

- Phantom RMI 156; MatNo: 088 81 265;
- Collimator-mounted Plexi;
- Dosimeter calibrated at the Mammo X-Ray beam energies (with Mammo Chamber);
- 3 x 20 mm plexi (PMMA) phantom; MatNo: 065 61 232 (150 x 150 x 19 mm)
MatNo: 065 61 224 (150 x 150 x 9,7 mm)
- 24 x 30 cm compression plate;
- 42 mm PMMA (350 x 350 mm): MatNo: 074 47 720;
- 2 mm thick steel plate (same size as the FFDM object table !);
- 2 mm small steel bars approx: 3 x 10 cm;
- Compression plate simulator;
- 4 paper clips;
- timer;
- magnification table (only if delivered);

Documents

All technical documents and User's manuals originally delivered with the Novation DR system.

Ordering Information

Since the update material is provided by HQ and carried along by the performing personnel there is no need to order materials.

Contents of the Update Kit

n.a.

Return of Parts

The HQ personnel will decide on site after disassembly what will happen to the removed parts.

Work Steps

A) Work steps to be performed before the actual assembly of the new power supply

- **Check detector for pixel dropout;**

This is a non-standard procedure. As help use the description of the detector gain calibration on Pages 34-36 of the Instruction for Use of Mammomat Novation DR, Print No: SPB7-250.201.01.01.02. Here the IDL program, available e.g. for the specialists of R&D is needed, as well as the FTP - File Transfer Protocol.

Proceed with the exposure according to points 1 through 6. Do not REJECT or ACCEPT the obtained image, but grab it from another networked workstation (e.g. MammoReport Plus, or Service PC). The image will serve only for visual assessment.

- **Measure (check) pixel value level;**

This is a non-standard procedure. As help use the Pages 17 & 18, Chapter 8 of the "DirectRay for Siemens FFDM Acquisition Workstation Software User's Manual" - Dec. 9th 2003; expose an image with the 42 mm PMMA phantom on detector. Proceed viewing ROI information according to Point 1/ Page 17. Choose box size 128 x 128. Note down the mean (pixel level) value of the ROI statistics pop-up tag. Repeat four to five times, calculate the average value of the displayed mean pixel value levels and note it down.

B) Exchange / assembly of the new power supply;

1. Purpose:

This SOP describes the method for converting the FFDMS to Extended High Voltage Power Supply (EHVPS).

2. Other documents:

DRP15002 ESD Control Requirements.

3. Tools, equipment and materials:

see page 3.

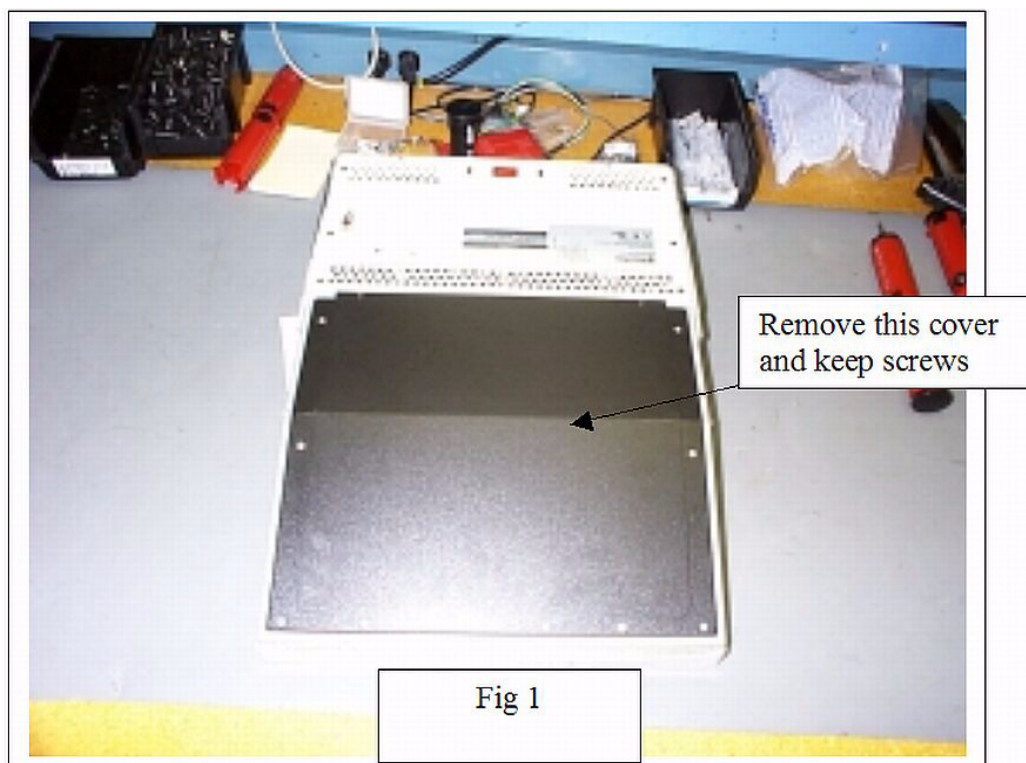
4. Ergonomic, material, and safety concerns:

Follow all building safety procedures.

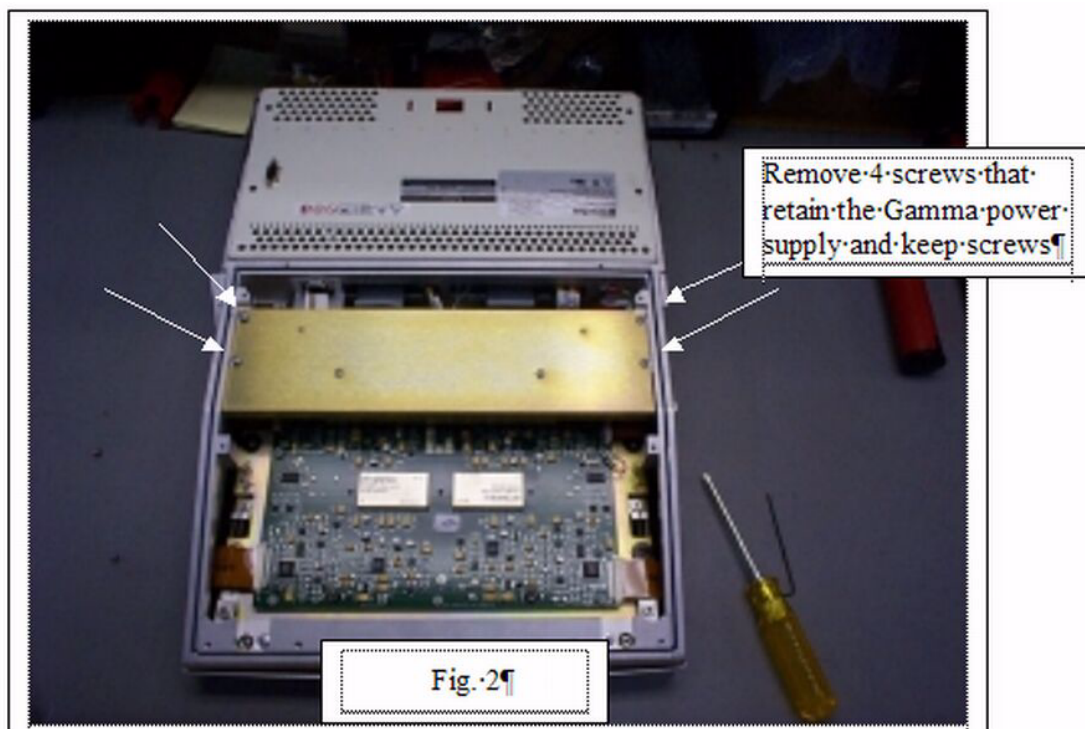
5. Process Steps:

5.1 Remove Gamma Power Supply

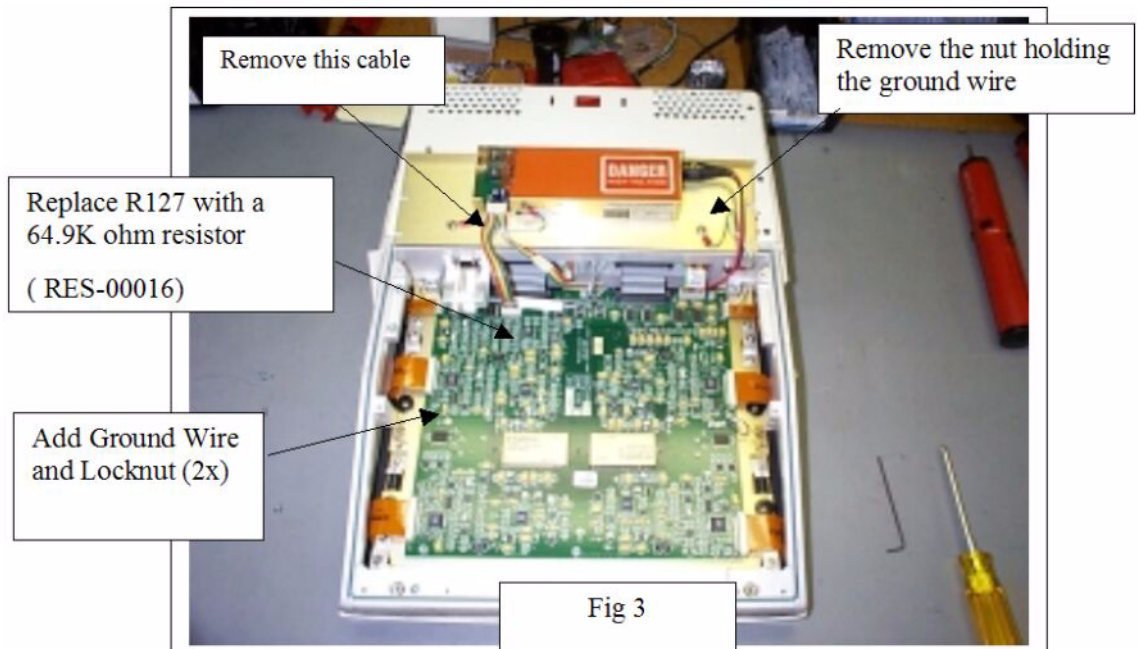
5.1.1 Remove the screws from the bottom cover as shown in Fig 1.



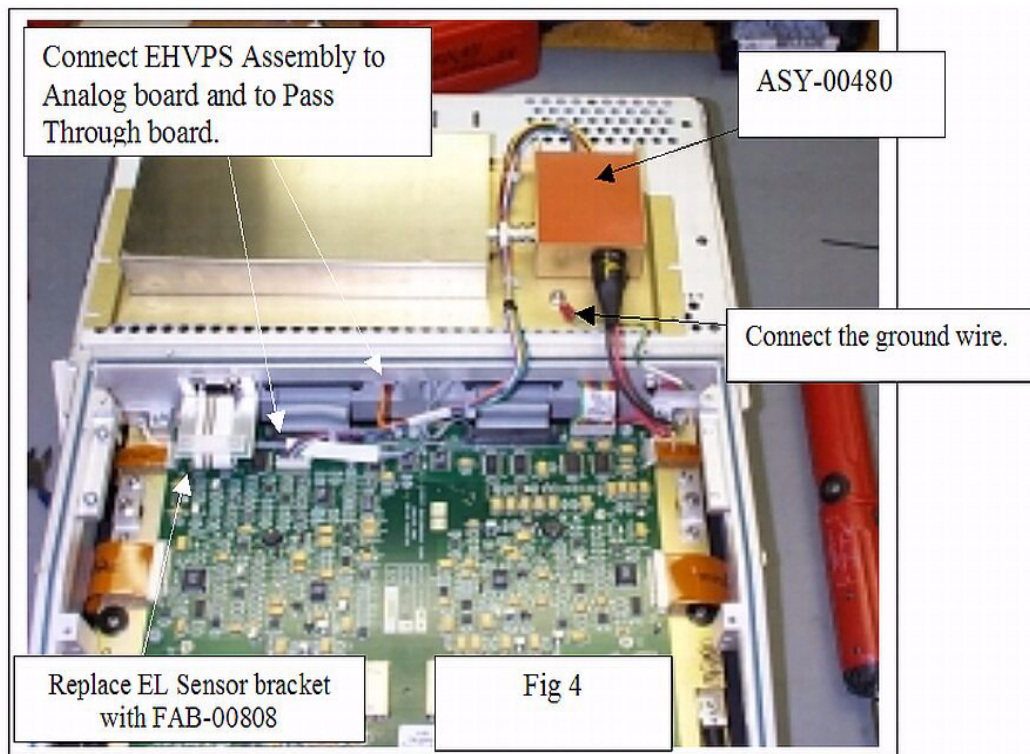
5.1.2 Remove the four screws retaining the Gamma power supply. See Fig. 2.



- 5.1.3 Remove the cable harness that connects the power supply to the analog board. See Fig 3.
- 5.1.4 Disconnect the High Voltage cable from the Gamma power supply.
- 5.1.5 Remove the Gamma power supply.

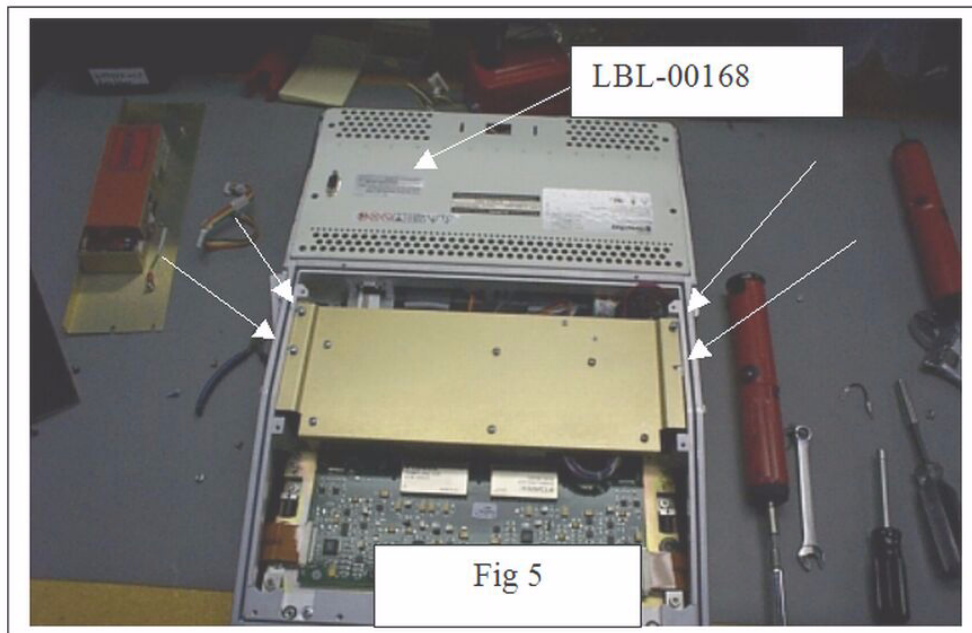


- 5.1.6 Change R127 to 64.9K ohm resistor (RES-00016)
- 5.1.7 Place a new Part Number label on the analog board indicating PCB-00029.
- 5.1.8 Add black ground wire (648122001) and 2 LKNT, Hex, #4-40, w/Nylon Insert (700436002) to ground the analog board to the base plate, see Fig 3.
- 5.1.9 Place EHVPs Unit Assembly (ASY-00480) upside down on top of the Electrical Box Assembly. See Fig. 4.
- 5.1.10 Connect the cable harness to the Pass Through board and to the Analog board. See Fig. 4.



- 5.1.11 Connect the High Voltage cable to the EHVPS unit. See Fig 4.
- 5.1.12 Connect the ground wire to the EHVPS unit ground stud. See Fig 4.
- 5.1.13 Remove EL Sensor bracket and replace with FAB-00808.

5.1.14 Fasten the EHVPs Unit in place with the original four screws. See Fig 5.



5.1.15 Add Software/Firmware Label (LBL-00168) see Fig 5.

5.1.16 Replace bottom cover with new Bottom Front Cover Assembly (ASY-00489).

C) Work steps to be performed after the actual assembly of the new power supply, described under previous point B.

- **Perform Detector gain calibration;**

1. this can be done according to Page 20 - 1 of the Installation and Start-Up Instructions - SPB7-250.812.01.02, or
2. according to Pages 7-14 through 17 of the DirectRay for Siemens FFDM Acquisition Workstation Software User's Manual / Dec. 9th 2003,
3. a reference can be found also on Page 6 - 1 of the DirectRay for Siemens (FFDM - S) Service manual, Febr. 5th 2004 (Preliminary draft), and
4. on Pages 34 through 36 of the Instructions for Use Mammomat Novation DR, Print No: SPB7-250.201.01.01.02.

- **Perform AEC Dark offset calibration;**

according to Pages 22 - 9 & 10 of the Installation and Start-Up Instruction - SPB7-250.812.01.02; Repeat for magnification mode (if table delivered).

- **Perform AEC - Calibration;**

according to Page 22 - 11, etc. of the Installation and Start-Up Instruction - SPB7-250.812.01.02; proceed as stated under Para "Generate goal image". Utilize the **AecCalTool**.

- **Measure (check) pixel value level -**

This is a non-standard procedure. As help use the Pages 17 & 18, Chapter 8 of the "DirectRay for Siemens FFDM Acquisition Workstation Software User's Manual" dated Dec. 9th 2003; expose an image with the 40 mm PMMA phantom on detector. Proceed viewing ROI information according to Point 1/ Page 17. Choose box size. Note down the mean (pixel level) value of the ROI statistics pop-up tag. Repeat four to five times, calculate the average value of the displayed mean pixel values levels and note it down.

Compare this with the value measured and calculated before the detector update. It can be expected that the value measured after the detector update should be higher. The AEC is set to a value of 1,5 mGy if the 42 mm PMMA phantom is on the detector. According to the difference between the pixel value level measured before and after the detector update with the new power supply, the AEC dose settings may have to be modified, i.e.: lowered (possibly in an iterative manner, see Point "Check pixel value level"). The aim is to achieve similar visual impression from the image (similar pixel value level) as before. Being the sensitivity of the detector enhanced the applied dose can possibly be lowered.

- **Check the AEC Dose settings, then Adjust the dose settings;**

proceed according to Pages 11 - 1 & 2 of the "Installation and Start-Up Instruction, Print No: SPB7-250.812.01.02; Check the H & D dose settings for target / filter combinations: Mo / Mo, then for Mo / Rh and W / Rh. Proceed via Netscape browser to adjust the H & D settings, this is described on Page 11 - 2; this adjustment has to be made in accordance with the relation between the pixel value level measured before and after the detector update.

- **Check pixel value level;**

The resulting pixel value level will change. Based on this actual average the previous step may need to be repeated. If the pixel value level is close to the previous one, the setting can be considered as acceptable. If it still falls far from the original value, the check and adjustment of the AEC dose settings will have to be repeated.

(For orientation: pixel value levels between 300 to 350 could be considered as an acceptable default.)

- **Proceed further with test No: 6, 8, 12, 13, 14, 15, 16, 18, of the Quality Control Manual.** (SPB7-250.210.01.01.02, but country-specific).

- **Perform Acceptance test** - usuall performed by the medical physicist, or by an expert from an Authorized Body.

Final Check

n.a.

Customer Information

n.a.

Final Work Steps

- Update the system documentation.
Update the revision level, the operating instructions and the technical documentation.
Fill out, and if needed, make a copy of the attached "Completion Protocol/ Update Completion Form" and file it in the corresponding System Binder/User Handbook.
- This update includes an IVK.
 - Changes in the IVK structure must be reported to the management system to correct the installed volume.
- Updates that have already been completed prior to publication of this SI must also be reported.
- The update is reported as follows:
 - Use a standard sentence
 - (- The update is reported as follows:
 - The modification reply cards (Type 606) previously distributed with the publication of updates no longer apply.
 - The modification reply report has to be prepared by authorized personnel using an application on the Intranet.)

Changes to Previous Version

n.a. new document.

Completion Protocol

The update with the number **SP005/04/P** has been completed.

Material number:

Serial number:

Customer: Functional Location:

Customer No.:

Name (CSE): Telephone:

Country: Location:

Date: Signature:

Remark:

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